IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

THE STATE OF TEXAS, *ex rel.* LAYNE D. FOOTE, MARK T. LORDEN, ROSEMARIE DE SOUZA and KENNETH MCDONOUGH, M.D.,	§	
Plaintiffs,	§	
V.	§	1-15-CV-102 RP
ASTRAZENECA, L.P., and ASTRAZENECA PHARMACEUTICALS, L.P.,	§	
Defendants.	§	

ORDER

Before the Court are Plaintiffs' Motion to Remand to Travis County District Court Pursuant to 28 U.S.C. § 1447, filed February 13, 2015 (Clerk's Dkt. #15); Memorandum in Opposition to Plaintiffs' Motion to Remand to Travis County District Court Pursuant to 28 U.S.C. § 1447, filed February 27, 2015 (Clerk's Dkt. #23); and Plaintiffs' Reply to Defendants' Opposition to Motion to Remand, filed March 12, 2015 (Clerk's Dkt. #25). After reviewing the parties' pleadings, relevant case law, as well as the entire case file, the Court issues the following order.

I. BACKGROUND

Plaintiffs the State of Texas, by and through the Attorney General of Texas, and relators Layne D. Foote, Mark T. Lorden, RoseMarie De Souza and Kenneth McDonough, M.D. originally filed this action in the 353rd Judicial District Court of Travis County, Texas on August 7, 2013. They named as defendants Astrazeneca, L.P., and Astrazeneca Pharmaceuticals, L.P. (jointly "AstraZeneca").

Plaintiffs contend Defendants entered into a long-term, multi-year scheme to improperly promote the use of Crestor, a prescription drug belonging to a group of cholesterol-lowering medicines called "statins." Plaintiffs describe Crestor as a late arrival to the market, facing

significant safety concerns after receiving approval from the Food and Drug Administration ("FDA"). Specifically, Plaintiffs allege the FDA issued advisories in 2004 and 2005 regarding specific safety issues related to "kidney failure" and "myopathy" resulting from Crestor use. (Plf. 1st Am. Pet. ¶¶ 16-17). According to Plaintiffs, Defendants developed a three-part marketing scheme to overcome these issues, including: (1) asserting false and misleading claims that Crestor was superior to its chief rival at lowering bad cholesterol; (2) making the misleading and "off-label"[1] claim that Crestor was the only statin that could stop and even reduce or "regress" the development of plaque in the arteries (atherosclerosis); and (3) making the misleading and "off-label" claim that Crestor reduced the risk of death. (*Id*. ¶¶ 19-22, 52-98). Plaintiffs contend the misrepresentations of Defendants resulted in Crestor being placed on "Preferred Drug List" of the Texas Medicaid program and payment of excessive reimbursements for Crestor prescriptions to Defendants. (*Id*. ¶¶ 40-43, 52-98).

Plaintiffs assert solely state law causes of action, specifically violation of the Texas Medicaid Fraud Prevention Act, common law fraud, negligent misrepresentation, monies had and received and promissory estoppel, alleging Defendants acted improperly for the purpose of receiving benefits under the Texas Medicaid program. (*Id*. ¶¶ 99-134).

Defendants removed the action to this Court, asserting federal question jurisdiction, following the filing of Plaintiffs' First Amended Petition in state court. Plaintiffs have now filed a motion to remand this action back to state court. The parties have filed responsive pleadings and the motion is ripe for review.

II. STANDARD OF REVIEW

Federal courts have original jurisdiction over cases "arising under the Constitution, treaties or laws of the United States." 28 U.S.C. § 1331. A case may be removed to federal court if the

[1] Pharmaceuticals are approved by the FDA for specific uses. Uses for other purposes are referred to as "off-label."

action is one over which the federal court possesses subject matter jurisdiction. 28 U.S.C. § 1441(a). Implementation of this statute is controlled by the well-pleaded complaint rule. This rule provides that a "properly pleaded complaint governs the jurisdictional determination and if, on its face, such a complaint contains no issue of federal law, then there is no federal question jurisdiction." *Aaron v. Nat'l Union Fire Ins. Co.*, 876 F.2d 1157, 1160-61 (5th Cir. 1989). Stated differently, removal is proper if the complaint establishes: (1) federal law creates the cause of action; or (2) federal law is a necessary element of one of the well-pleaded claims. *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 808-09 (1988); *Franchise Tax Bd. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 27-28 (1983). When the propriety of removal is challenged, the burden of establishing federal jurisdiction is on the party who removed the action. *Miller v. Diamond Shamrock Co.*, 275 F.3d 414, 417 (5th Cir. 2001); *Frank v. Bear Stearns & Co.*, 128 F.3d 919, 921-22 (5th Cir. 1997).

II. DISCUSSION

The parties here agree Plaintiffs are asserting claims which are created by state law, rather than federal law. Defendants nonetheless maintain removal was proper because the claims fall into a "special and small category" of cases "in which arising under jurisdiction still lies" because the case raises a federal issue. *Gunn v. Minton*, __ U.S. __, 133 S. Ct. 1059, 1064-65 (2013); *Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 699 (2006). Specifically, federal jurisdiction over a state law claim will lie "if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." *Gunn*, 133 S. Ct. at 1065 (citing *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005)). The Fifth Circuit states the inquiry as whether "(1) resolving the federal issue is necessary to resolution of the state-law claim; (2) the federal issue is actually disputed; (3) the federal issue is substantial; and (4) federal

jurisdiction will not disturb the balance of federal and state judicial responsibilities." *Singh v. Duane Morris LLP*, 538 F.3d 334, 338 (5th Cir. 2008).

The threshold for this inquiry is identification of the federal issue underlying the asserted state law claims. In removing this action, Defendants pointed out that Plaintiffs' state court petition describes the FDA's regulatory scheme in detail and the prohibitions under the Food, Drug and Cosmetics Act ("FDCA") against "misbranding" of prescription drugs, as well as the federal statutory scheme for prescription drug reimbursement by Medicaid. Defendants maintain in the notice of removal that federal jurisdiction lies because the theory underlying all of Plaintiffs' claims rests on federal law. As our sister court has noted, however, "a state-law claim can involve federal subject matter without involving a substantial federal issue." *Windle v. Synthes USA Prods*., LLC, 2012 WL 1252550, at *7 (N.D. Tex. Apr. 13, 2012). The invocation of a federal regulatory scheme alone is not enough to create federal jurisdiction. *See RX.com, Inc. v. O'Quinn*, 766 F. Supp. 2d 790, 796 (S.D. Tex. 2011) (Supreme Court's opinions teach that "something more is required" to invoke federal jurisdiction "than the mere fact that the state court will be asked to follow federal standards in the context of adjudicating a state law claim.").

In opposing Plaintiffs' motion to remand, Defendants argue resolution of federal issues is necessary as the theory underlying Plaintiffs' claims is that AstraZeneca misbranded Crestor in violation of the FDCA, rendering the drug ineligible for reimbursement under Medicaid, thus interpretation of the FDCA and federal Medicaid statutes is necessary to determine the validity of Plaintiffs' claims. Plaintiffs maintain resolution of federal issues is not necessary because they have also asserted AstraZeneca's conduct violated state law. The Court is not wholly convinced the presence of alternative bases for recovery renders the resolution of federal issues in this action unnecessary. However, the question need not be resolved because the presence of the first requirement under *Grable* and *Singh* alone is not dispositive.

Defendants also maintain the second and third requirements for federal question jurisdiction

are satisfied as the federal issue is both actually disputed and substantial. According to Defendants, whether AstraZeneca engaged in off-label marketing that violated the FDCA is the central issue in this case, thus interpretation of the FDCA is both disputed and substantial. Plaintiffs, in turn, maintain the dispute here is not the legal interpretation of the FDCA, rather the dispute is whether factually AstraZeneca violated federal drug regulations.

The Supreme Court addressed this concept in *Grable*, noting while "violation of federal statutes and regulations is commonly given negligence per se effect in state tort proceedings," that was insufficient to transform those proceedings into matters to be litigated in federal court. *Grable*, 545 U.S. at 318-19. *See also Singh*, 538 F.3d at 338-39 (rejecting argument that state malpractice claim based on conduct of attorney in federal trademark action presented disputed and substantial federal issue because dispute was predominantly one of fact). According to Defendants, the federal issue is "disputed" because they dispute Plaintiffs' ability to recover based on the allegations that promotion of Crestor for regression of atherosclerosis is "misbranding" because such use was in fact medically indicated. This dispute, however, is not one of law as the parties agree medically indicated uses are not off-label and do not constitute misbranding. Rather, Defendants' argument points to a factual dispute concerning whether Cretro was medically indicated for regression of atherosclerosis.

Defendants also maintain there is a disputed and substantial issue of federal law because Plaintiffs are seeking disgorgement of the revenues from reimbursements for Crestor prescriptions from AstraZeneca's alleged off-label promotion of Crestor. Defendants argue the heart of this request will require resolution of issues of federal Medicaid law and the propriety of prescription drug reimbursement thereunder. Defendants rely on a case in which the court denied remand of a case asserting state law claims by a state attorney general that a drug manufacturer "devised elaborate schemes" for marketing prescription medication for "off-label" uses. The court found federal jurisdiction existed because the question of the state's obligation to reimburse its insured

for prescriptions drugs, using funds largely provided by the federal government, is essential to the state's theory of damages and presents an unavoidable central and disputed federal issue. *In re Zyprexa Prods. Liab. Litig*., 2008 WL 398378, at *3-4 (E.D.N.Y. Feb. 12, 2008).

As Plaintiffs point out, the judge in the *Zyprexa* case recognized there is a split of authority, noting federal district courts in four other states had remanded virtually identical cases. *Id*. at *4. Moreover, the Court finds the analysis in the *Zyprexa* case flawed in part. Specifically, the court's conclusion that the claim that marketing Zyprexa for off-label uses constituted a violation of federal law "necessarily raise[d] substantial federal questions" appears contrary to Supreme Court precedent. *See Grable*, 545 U.S. at 318-19 (noting negligence allegation resting on violation of federal statutes or regulations would be insufficient to transform proceedings into matters to be litigated in federal court); *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 817 (1986) (complaint alleging violation of federal statute as element of state cause of action does not state claim "arising under" federal law, rejecting argument that unsettled question regarding application of FDCA to foreign sales raised substantial federal question).

The Court thus concludes Defendants have failed to point to a disputed and substantial federal issue requiring resolution in this case. Absent such an issue, Defendants have failed to establish federal question jurisdiction. This conclusion is in line with other decisions of federal district courts in the Fifth Circuit. *See Louisiana v. Pfizer, Inc.*, 2014 WL 3541057 (M.D. La. July 17, 2014) (remanding case asserting state law claims based on allegations that drug manufacturer engaged in extensive scheme to deceptively and deliberately conceal drug's true efficacy to mislead State and healthcare providers); *Windle*, 2012 WL 1252550, at *7-8 (allegations that medical device marketing violated multiple federal requirements, circumvented warning process required by FDA, and included labeling in direct violation or contravention of FDA requirements not sufficient to confer federal question jurisdiction); *Caldwell ex rel. Louisiana v. Bristol Myers-Squibb Sanofi Pharm. Holding P'ship*, 2012 WL 3866493 (W.D. La. Sept. 4, 2012) (adopting report and

recommendation) (remanding case brought by state attorney general alleging defendant drug manufacturer used false and misleading advertising to promote sale of drug, resulting in state's purchase of drug for Medicaid recipients to whom drug should not have been prescribed); *In re Vioxx Products Liab. Litig.*, 843 F. Supp. 2d 654, 669 (E.D. La. 2012) (declining to find federal question jurisdiction where allegations invoked conduct regulated by FDA); *McAdams v. Medtronic, Inc.*, 2010 WL 3909958, at *4 (S.D. Tex. Sept. 29, 2010) (concluding question of whether medical device manufacturer complied with FDA standards with respect to device was important to parties, but did not implicate substantial federal interest). *See also Williams v. Edcare Mgmt., Inc.*, 2008 WL 4755744, at *8 (E.D. Tex. Oct., 28, 2008) (remanding case, finding reference to alleged violations of federal Medicare laws, in support of state law causes of action not sufficient to raise substantial questions of federal law). Accordingly, this case should be remanded to Texas state court.

IV. CONCLUSION

The Court hereby **GRANTS** Plaintiffs' Motion to Remand to Travis County District Court Pursuant to 28 U.S.C. § 1447 (Clerk's Dkt. #15).

IT IS THEREFORE ORDERED that this cause is **REMANDED** to the 353rd Judicial District Court of Travis County, Texas.

SIGNED on March 30, 2015.

ROBERT L. PITMAN
UNITED STATES DISTRICT JUDGE